

REQUEST FOR EXEMPTION OF SELECT AGENTS AND TOXINS FOR AN INVESTIGATIONAL PRODUCT (APHIS/CDC FORM 5)

FORM APPROVED OMB NO. 0579-0213 OMB NO. 0920-0576 EXP DATE 11/30/2015

Read all instructions carefully before completing the form. Answer all items completely and type or print in ink. The form must be signed and submitted to either APHIS or CDC:

Animal and Plant Health Inspection Service Agricultural Select Agent Program 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07 Riverdale, MD 20737

FAX: 301-734-3652

E-mail: ASAP@aphis.usda.gov

Centers for Disease Control and Prevention Division of Select Agents and Toxins 1600 Clifton Road NE, Mailstop A-46 Atlanta. GA 30333

FAX: 404-718-2096 Email: lrsat@cdc.gov

SECTION 1 – TO B	E COMPLETED FOR INVESTIGA	ATIONAL PRODUC	CT EXEMPTION	
1. Entity name:		2. Entity registration number (if applicable):		
3. Entity address (NOT a post office address):		4. City:	5. State:	6. Zip code:
7. Applicant First: MI: Last:		8. Title:		
9. Telephone #:	10. FAX #:	11. Email address:		
12. FDA IND/INAD/IDE number:	13. FDA product name:	14. This product has been approved for Phase I clinical trials by FDA: ☐ No ☐ Yes		
15. Date of the IND/INAD/IDE application subr FDA Center/Review Office:		DA center and review on ate:	office	
16. USDA veterinarian product code number:	17. USDA veterinarian product name:	18. This product has been tested and approved for field trials by USDA: ☐ No ☐ Yes		
19. Investigational product (Give select agent n	ame and characterization):			
20. Federal act that authorizes investigational u	use of this product:			
(attach additional sheets if necessary):				
I hereby certify that the information contained of statement on any part of this form, or its attach 331, 9 CFR 121, or 42 CFR 73 may result in ciproduct that is, bears, or contains select agent and agree that such confirmation will not violat Act (18 U.S.C. § 1905).	ments, I may be subject to criminal fines ivil or criminal penalties, including impriso s or toxin, I authorize FDA to confirm for A	and/or imprisonment. Inment. For exemption APHIS or CDC the exis	I further understand that requests that involve the tence and status of the I	violations of 7 CFF e investigational ND, INAD, or IDE,
Signature of Investigational Product Exemption	Date:			
Public reporting burden: Public reporting bur	den of this collection of information is est	imated to average 1 ho	our per response, includir	ng the time for

Public reporting burden: Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).

APHIS/CDC FORM 5 (11/30/2015)